United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

RICHARD CONNELLY,

Plaintiff,

v.

ST. JUDE MEDICAL, INC., et al.,

Defendants.

Case No. 5:17-cv-02006-EJD

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS

Re: Dkt. No. 29

Plaintiff Richard Connelly brings claims against Defendants St. Jude Medical, LLC, Abbott Laboratories, and Pacesetter, Inc. (together, "St. Jude") arising from injuries he suffered from allegedly defective medical devices. St. Jude moves to dismiss under Fed. R. Civ. P. 8(a) and 12(b)(6) on the grounds that Connelly's claims are insufficiently pled and preempted by federal law. St. Jude's motion will be granted in part and denied in part.

I. BACKGROUND

In 1976, Congress enacted the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). The MDA gave the Food and Drug Administration ("FDA") authority to regulate medical devices. Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008).

Medical devices that support human life, or pose a high risk of illness or injury, are known as Class III devices. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 344 (2001). Manufacturers must apply for and receive premarket approval ("PMA") from the FDA before they can sell Class III devices. Id. The FDA grants approval after a rigorous review process. Riegel, 552 U.S. at 317. After a device has received approval, the manufacturer may not make changes that would affect the device's safety or effectiveness without applying for and receiving supplemental approval (a "PMA Supplement") from the FDA. Id. at 319. The manufacturer is required "to report incidents [to the FDA] in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." Id.

St. Jude manufactures Class III devices called Riata Leads. Compl. ¶¶ 1, 32, Dkt. No. 1. Riata Leads allow an implantable cardiac defibrillator ("ICD") to detect a patient's abnormal heartbeat and deliver an electric shock to restore a normal heartbeat. Id. ¶ 1.

In 1996, the FDA approved St. Jude's PMA application for an ICD lead called the Ventritex VTI Lead. Id. ¶ 34. St. Jude sought and obtained supplemental approval several times in the following years. Id. In 2002, the FDA approved St. Jude's fourteenth PMA Supplement, which approved design modifications and allowed the leads to be marketed under the Riata name. Id. ¶ 35; Defs.' Mot. to Dismiss ("MTD") 5, Dkt. No. 29.

Connelly alleges that his doctors surgically installed Riata Leads and connected them to his heart in May 2003 (and again in 2007 and 2015). Compl. ¶¶ 3, 35. St. Jude's fifteenth and sixteenth PMA Supplements had been approved before then, and the sixteenth supplement was approved in July 2003. Id. ¶ 88; MTD 5.

Starting in October 2005, St. Jude conducted an internal audit to examine "inside-out abrasion" associated with malfunctioning Riata Leads. Compl. ¶¶ 56–57. The "audit concluded that Riata Leads had potentially serious insulation problems." Id. ¶ 58. In 2009, the FDA conducted an inspection of St. Jude's facilities and issued a "Form 483 report" that identified possible "violation[s] of the FDCA and related Acts." Pl.'s Opp'n to Mot. to Dismiss ("Opp'n") 7, Dkt. No. 35; Compl. ¶¶ 59–63.

In 2010, St. Jude published a "Dear Doctor" letter that identified defects in certain Riata Lead models, including the model that was implanted in Connelly. Compl. ¶ 74. St. Jude published an updated letter in November 2011. Id. ¶ 76. In December 2011, the FDA reclassified the letter as a product recall, indicating that "failures associated with lead insulation abrasion on the St. Jude Riata and Riata ST Silicone Endocardial Defibrillation Leads may cause the conductors to become externalized. If this occurs, this product may cause serious adverse health consequences, including death." Id. ¶¶ 77–78.

Plaintiff alleges that, in November 2016, his Riata leads malfunctioned while he slept. Id. ¶ 92. He "was shocked an estimated sixteen to twenty times, causing irreparable harm to his heart, body, and mind." Id. He underwent surgery in March 2017 to replace the faulty lead. Id. ¶ 95.

Connelly brings causes of action for (1) strict liability—manufacturing defect (Compl. ¶¶ 97–103), (2) strict liability—failure to warn (Compl. ¶¶ 104–15), (3) negligence per se (Compl. ¶¶ 116–23), and (4) negligence (Compl. ¶¶ 124–29). St. Jude now moves to dismiss.

II. LEGAL STANDARD

A motion to dismiss under Fed. R. Civ. P. 12(b)(6) tests the legal sufficiency of claims alleged in the complaint. Parks Sch. of Bus., Inc. v. Symington, 51 F.3d 1480, 1484 (9th Cir. 1995). Dismissal "is proper only where there is no cognizable legal theory or an absence of sufficient facts alleged to support a cognizable legal theory." Navarro v. Block, 250 F.3d 729, 732 (9th Cir. 2001). The complaint "must contain sufficient factual matter, accepted as true, to 'state a

claim to relief that is plausible on its face.' " Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

III. DISCUSSION

St. Jude argues that Connelly's complaint must be dismissed because (1) three of his claims are expressly preempted, (2) one of his claims is impliedly preempted, and (3) all of his claims are insufficiently pled.

A. Manufacturing-Defect Claim

St. Jude argues that Connelly's manufacturing-defect claim is expressly preempted under § 360k(a) of the MDA, which states:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added); see MTD 8–18. Its implementing regulation provides:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.... The following are examples of State or local requirements that are not regarded as preempted by [§ 360k]:
>
> . . . .
>
> (2) [Section 360k] does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

21 C.F.R. § 808.1(d).

Courts apply a two-step test to determine whether state-law claims are expressly preempted

under § 360k(a). Riegel, 552 U.S. at 322–23. First, the court determines whether "the Federal Government has established requirements applicable to" the particular medical device. Id. at 321. If so, the court determines whether the state-law claim would impose "requirements with respect to the device that are 'different from, or in addition to,' " the federal requirements. Id. at 322. The state-law claim is explicitly preempted if both conditions are satisfied. Here, Connelly concedes that St. Jude has satisfied the first prong of the Riegel test (i.e., Connelly agrees that the PMA and PMA Supplements are federal requirements that are applicable to Riata Leads). Opp'n 15. However, Connelly argues that his claims are not preempted because they parallel the federal requirements.

Connelly bases his manufacturing-defect claim on five defects that he alleges violated St. Jude's PMAs:

> Inconsistent insulation diameters surrounding the electric conductors. Defendants failed to manufacture uniform insulation diameters leading to an increased risk of abrasion at thinner insulation sites, as well as externalization, which leads to an increased risk of device failure.
>
> Inconsistent application of a lubricious interface between the inner and outer insulation in violation of the design specifications and/or the PMAs. This inconsistent application may have led to increased friction within the lead body, promoting abrasion and/or externalization.
>
> Failure to comply with the approved methods and/or specifications of curing during the manufacture of the Riata Leads. Defendants failed to follow the approved cure processes, resulting in reduced tensile strength of the silicone insulation.
>
> Failure to comply with the approved methods and/or specifications of sterilization during the manufacture of the Riata Leads. Defendants failed to follow the approved sterilization processes, resulting in reduced tensile strength of the silicone insulation.
>
> Failure to crimp with a controlled, uniform, degree of force, resulting in insecure crimps over the length of the Riata Leads.

Opp'n 15–16 (citing Compl. ¶¶ 66–70).

St. Jude argues that Connelly's claims are preempted because four of these five

requirements do not exist in the PMA and PMA Supplements for the relevant Riata Leads. MTD 10–12. Claims based on these nonexistent requirements, St. Jude's argues, are preempted because they necessarily impose requirements that are "different from, or in addition to," the federal requirements. Id.

Plaintiffs face a dilemma when pleading claims that a manufacturer violated PMA requirements. Because they contain confidential information, PMAs are not publicly available in their entirety. Opp'n 16. The public can view a PMA's ID number, its date, and a brief description of its contents, but the full contents of the PMA are not publicly disclosed. See Rosen v. St. Jude Med. Inc., 41 F. Supp. 3d 170, 178 (N.D.N.Y. 2014). So, without knowing the specific contents of a PMA, a plaintiff must nonetheless plead a violation of PMA requirement in enough detail to avoid preemption under § 360k and to satisfy federal pleading requirements.

The Ninth Circuit has not directly addressed this issue, although a number of other district and appellate courts have considered the level of detail a plaintiff must provide when pleading PMA violations. See id. at 178–81 (collecting and synthesizing relevant cases). This Court finds the Rosen court's reasoning persuasive, and agrees that "where a plaintiff has limited access to the PMAs at the time she files her complaint, allegations that the defendant violated [PMAs], so long as they are supported by sufficient factual evidence and demonstrate a causal connection to the alleged injuries, are all that is required to satisfy Twombly and avoid preemption under § 360k and Riegel." Id. at 181 (emphasis in original); accord Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830, 838 (S.D. Ind. 2009).

St. Jude argues that Connelly's complaint is "devoid of any facts that would plausibly suggest that St. Jude ever violated any of the purported requirements." MTD 13. However, Connelly's complaint identifies specific facts from an internal St. Jude audit, three FDA enforcement actions, two Dear Doctor Letters, and the 2011 Class I recall of the Riata Leads.[1]

[1] St. Jude asks the Court to adopt factual findings from Pinsonneault v. St. Jude Medical, Inc., No 12-cv-1717, 2014 WL 2879754 (D. Minn. June 24, 2014). The Court declines to do so because Pinsonneault involved a motion for summary judgment, not a motion to dismiss. Unlike here, the

Opp'n 16 (citing Compl. ¶¶ 56–83). Together, this evidence suggests that St. Jude violated the requirements contained in the applicable PMAs. Connelly has also demonstrated a plausible connection between the alleged manufacturing defects and his injuries. Accordingly, the Court finds that Connelly has sufficiently alleged a parallel state claim that survives preemption under Riegel and § 360k(a).

B. Negligence Claim

St. Jude argues that Connelly's negligence claim is expressly preempted and inadequately pleaded "for the same reasons as Plaintiff's strict-liability manufacturing defect claim." MTD 18, 24; Defs.' Reply in Support of Mot. to Dismiss ("Reply") 11, 15. Connelly states that his arguments regarding his manufacturing-defect claims "apply with equal force" to his negligence claims.

Having found that Connelly has adequately stated non-preempted claims for manufacturing defects, the Court also finds that Connelly's negligence claim is sufficient to survive St. Jude's motion to dismiss.

C. Failure-to-Warn Claim

Manufacturers of Class III devices have a duty to "report incidents [to the FDA] in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." Riegel, 552 U.S. at 319. Here, Connelly alleges that "from 1997 through at least November 2016, Defendants failed to comply with their duty to file adverse-event reports with the FDA and, at the same time, breached their state law duty to warn of dangerous product defects." Opp'n 17–18.

St. Jude acknowledges that the Ninth Circuit has found that similar failure-to-warn claims are not expressly preempted. MTD 14–15 (citing Stengel v. Medtronic, 704 F.3d 1224 (9th Cir. 2013)). However, St. Jude argues Connelly's failure-to-warn claim nevertheless fails because

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parties in Pinsonnseault had conducted discovery, and the court was not required to accept the plaintiff's allegations as true.

Connelly has not identified specific adverse events that St. Jude knew of but failed to report, and Connelly has not established a causal link between St. Jude's alleged failure to warn and Connelly's injuries. MTD 15–18; Reply 8–11.

Connelly correctly notes that the PMA for the Riata Leads' predecessor was first approved in 1996. Opp'n 20. In 2002, the fourteenth PMA Supplement approved the type of Riata Leads that were implanted in Connelly. Id. Connelly's leads were surgically implanted in 2003. Id. On this basis, Connelly argues:

> As alleged in the Complaint, notwithstanding multiple reports of inside-out abrasion from doctors and internal audits regarding the same, St. Jude failed to make the required disclosures to the FDA. See, e.g., Complaint, ¶¶ 8, 56-58, 60-62, 73.

Id. Connelly argues that, if St. Jude had reported these events to the FDA, Connelly's "physicians would never have installed the devices and [he] would never have been damaged." Id.

However, Connelly's allegations refer exclusively to adverse events that occurred after the Riata Leads were implanted in him (in 2003). See Compl. ¶¶ 8 ("No later than 2005 and likely sooner, Defendants realized the Riata Leads were defective"), 56–58 (referring to incidents that occurred in 2005 and 2008), 60–62 (referring to the results of FDA inspections that were made available in 2009), 73 (referring to a 2010 Dear Doctor letter).

None of these allegations suggest that St. Jude failed to report known adverse events before Connelly's Riata leads were implanted in 2003. Connelly's allegation that St. Jude knew of defects "[n]o later than 2005 and likely sooner" (Compl. ¶ 8) is insufficient because Connelly provides no factual basis for his claim that St. Jude knew of defects in Riata Leads, but failed to report them to the FDA, before 2005.

As such, the Court finds that Connelly has failed to establish a causal connection between Connelly's injuries and St. Jude's failure to warn. Connelly's failure-to-warn claim will be dismissed with leave to amend.

D. Negligence-Per-Se Claim

Connelly's negligence-per-se claim is based entirely on violations of the FDCA and its

implementing regulations. Compl. ¶ 118. St. Jude argues that claims that exist solely by virtue of FDCA requirements are impliedly preempted under § 337(a) because the federal government has exclusive authority to enforce FDCA requirements. Reply 12; see also Buckman, 531 U.S. at 353 (holding that claims were impliedly preempted because they "exist solely by virtue of the FDCA disclosure requirements"). Connelly attempts to limit Buckman to fraud-on-the-FDA claims. Opp'n 22–23. But St. Jude argues that courts routinely interpret Buckman to preempt a variety of other types of claims. See Reply 12 (collecting cases); see also, e.g., Martin v. Medtronic, Inc., 32 F. Supp. 3d 1026, 1034 n.22 (D. Ariz. 2014) ("Plaintiffs suggest that Buckman only applies to fraud-on-the-FDA claims because that was the claim at issue in that case, but Buckman cannot be read that narrowly.")

The Court agrees with St. Jude that there is "no material distinction between [Connelly's] claims and those held impliedly preempted in Buckman." Reply 12. As such, Connelly's negligence-per-se claim will be dismissed with leave to amend.

E. Abbott as a Defendant

Connelly alleges that Abbott Laboratories is liable as the successor in interest to St. Jude Medical, Inc. Compl. ¶ 2. St. Jude states that, according to publicly available Form 8-K records, St. Jude Medical, Inc. merged with a subsidiary of Abbott to create a new, separate entity: St. Jude Medical, LLC. MTD 24–25. St. Jude argues that St. Jude Medical, LLC—not Abbott Laboratories—is the successor in interest of St. Jude Medical, LLC. Id. On that basis, St. Jude argues that Abbott Laboratories is not a proper defendant in this action and must be dismissed. Id.

Connelly responds that Abbott is a proper defendant because the Abbott–St. Jude merger occurred on April 27, 2016, but Connelly was not injured until six months later. Opp'n 25. Connelly argues that "each Defendant"—including Abbott—"had an ongoing duty of care to [Connelly] under the negligence claim." Id.

St. Jude points out that Connelly has apparently abandoned his successor-liability theory in favor of a negligence theory. Reply 15. Even under a negligence theory, however, St. Jude argues

that Abbott is not a proper defendant because the merger was announced on April 27, 2016,[2] but it was not closed until January 5, 2017—nearly two months after Connelly's injuries occurred. Id.

The Court finds that Abbott Laboratories must be dismissed as a defendant. However, Connelly may amend his complaint to clarify the basis on which he believes Abbott may be held liable.

IV. CONCLUSION

St. Jude's motion to dismiss is DENIED as to Connelly's claims for manufacturing defects and negligence. St. Jude's motion to dismiss is GRANTED with leave to amend as to Connelly's claims for failure to warn and negligence per se. Abbott Laboratories is dismissed as a defendant with leave to amend to explain why Abbott is a proper defendant. Connelly shall file an amended complaint by September 8, 2017.

IT IS SO ORDERED.

Dated: August 23, 2017

EDWARD J. DAVILA
United States District Judge

[2] St. Jude's reply brief states that the merger was announced on April 27, 2017. This appears to be a typo. The context makes clear that the merger was announced on April 27, 2016.